

REMARKS

I. Claim Amendments

By the foregoing amendments to the claims, claims 1 and 26 have been amended to clarify that the at least two different affinity molecules in the liquid carrier each have affinity for a different predetermined anylyte. Support for these amendments can be found at least at page 6, lines 22-35, and page 7, lines 1-4, of the present specification. Further amendments have been made to claims 2-6, 16, 25, 27-29, and 31-34 to correct formal matters. These amendments are merely editorial in nature and are not intended to change the scope of the claims or any elements recited therein.

The amendments to the claims have been made without prejudice or disclaimer to any subject matter recited or canceled herein. Applicants reserve the right to file one or more continuation and/or divisional applications directed to any canceled subject matter. No new matter has been added, and entry of the foregoing amendments to the claims is respectfully requested.

II. Response to Claim Rejections Under 35 U.S.C. § 103(a)

A. Claims 1-5 and 25-32 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Willner, WO Application Publication No. 2000/43774, in view of Provonost, U.S. Patent No. 5,047,326.

B. Claims 16 and 33-34 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Willner in view of Provonost, and further in view of Boguslaski et al., U.S. Patent No. 5,420,016.

C. Claim 6 has been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Willner and Provonost, and further in view of Strahilevitz, U.S. Patent No. 4,375,414.

These rejections are respectfully traversed.

Initially, Applicants note that there is a difference between the words “analytes” and “antigens”. The word “analytes” is plural of analyte which means something that is or is to be analyzed. Therefore “analytes” indicates that there are two or several different analytes that are or are to be analyzed. The word “antigens” is plural of antigen which means an immunological

target that can elicit antibodies in a living organism. Therefore “antigens” indicates that there may be one, two or several immunological targets for eliciting antibodies. However, these targets may be in the same analyte, as in a bacterium to be detected by analysis.

The Examiner acknowledges that Willner does not teach a mixture of at least two different unlabeled antibodies. Applicants agree.

The Examiner cites column 4, lines 25-37, of Provonost to show a competitive immunoassay that utilizes a mixture of different antibodies, in order to detect the presence of multiple antigens corresponding to different biological entities.

The cited passage is as follows:

Examples of useful assays include competitive immunoassays or enzyme-linked immunoabsorbent assays (or what is commonly called "ELISA"). Such assays are described generally in U.S. Pat. No. 4,427,782 (noted above) and by Schmeier et al, J. Clin. Microbiol., 15(5), pp. 830-834 (1982). The chlamydial or gonococcal antibodies used can be directed to either or several antigens being extracted from the organisms. In one embodiment, antibodies are directed to a single antigen, such as the lipopolysaccharide of the *C. trachomatis*. In other embodiments, a mixture of different antibodies is directed to several antigens, such as those extracted from several gonococcal strains.

In this passage, Provonost has stated that “[t]he chlamydial or gonococcal antibodies used can be directed to either or several antigens being extracted from the organisms”. In other words, either chlamydial **or** gonococcal antibodies are contemplated – not both in the same solution.

The reference has also stated that “[a] mixture of different antibodies is directed to several antigens, such as those extracted from several gonococcal strains.” There is no background given to this sentence nor is there any indication of the possibility of having antibodies directed to different analytes (here is only mentioned several gonococcal strains, i.e. the possibility of detecting one analyte, namely the presence in a specimen of the analyte gonococcal bacteria).

Therefore, Applicants disagree with the Examiner’s interpretation of Provonost. In particular, Applicants do not agree that the cited passage describes “a competitive immunoassay that utilizes a mixture of different antibodies in order to detect the presence of multiple antigens corresponding to different biological entities”. Instead, there is no indication in the whole document of **one** assay for **separate** detection of the presence of multiple analyte antigens.

There is another passage in Provonost that mentions a single antibody or mixture thereof, namely column 7, lines 9-20:

The chlamydial or gonococcal antibody used in this assay is specifically immunoreactive with one or more chlamydial or gonococcal strains (depending upon what organism is of interest). It can be polyclonal or monoclonal. If polyclonal, it is commercially available or prepared in various animals using known techniques employing an antigen common to the strain of organism to be detected. A single antibody or mixture thereof can be used. For example, antibody to either the chlamydial lipopolysaccharide or major outer membrane protein antigen, or antibodies to both antigens can be used in the assay. Preferably, the antibodies are monoclonal...

Here only one antibody is used, the chlamydial or gonococcal antibody. The antibody is reactive with one or more chlamydial or gonococcal strains. It can be polyclonal or monoclonal. If polyclonal, it is commercially available or prepared in various animals using known techniques employing an antigen common to the strain of organism to be detected. That is, the polyclonal antibody is raised in various animals against an antigen common to the strain of organism to be detected, i.e. the analyte. For example, an antibody to either the chlamydial lipopolysaccharide or major outer membrane protein antigen, or antibodies to both antigens can be used in the assay. From this passage there is no way of concluding that if two different antibodies directed to different analytes are used in **one** assay, these are simultaneously used in one and the same solution in the contemplated assay. The most likely situation would be that the antibodies are held in different solutions and are added separately as in the previously cited Brooker patent, U.S. Patent No. 4,128,628.

One would expect that if Provonost had utilized a mixture of unlabeled antibodies in one liquid carrier in order to detect the presence of multiple analytes, this would be mentioned in the claims and also specifically exemplified in the specification. Therefore a person of ordinary skill in the art would have concluded that this reference does not teach or suggest the subject matter of the present claims, either alone or in combination with the cited Willner patent.

Finally, neither Boguslaski et al. nor Strahilevitz remedy the serious deficiencies of Willner and Provonost.

In view of the above, Applicants respectfully request reconsideration and withdrawal of these rejections.

CONCLUSION

In view of the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited.

In the event that there are any questions related to this response, or the application in general, it would be appreciated if the Examiner would telephone the undersigned attorney at the below-listed telephone number concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,

By: 
Lisa E. Stahl, Ph.D.
Registration No. 56,704

BACON & THOMAS PLLC
625 Slaters Lane, Fourth Floor
Alexandria, Virginia 22314-1176
703.683.0500

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